

Progress Update: CMDv/Industry Joint Task Force on Variations

2015 EMA/IFAH-Europe Info Day

13 March 2015

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Topics

- What is this Joint Task Force (JTF)?
- Composition of the JTF
- Plans for the JTF
- Possible topics
- First JTF meeting



What is this Joint Task Force?

- At Variations Workshop in June, 2014 Industry presented various on-going issues with variations and proposed possible solutions.
- As part of the proposed solutions, an appeal was made for CMDv to work jointly with industry to find workable solutions that could help all involved.
- After the workshop, a suggestion was offered to consider a “small” work group rather than the full workshop format – goal to be more efficient.
- Industry considered this idea and officially proposed it to CMDv.
- CMDv agreed and the Joint task Force (JTF) was formed.



Composition of the JTF

- CMDv:
 - Carmen Pilar Sánchez Mascaraque (ES)
 - Wiebke Godow (DE)
 - Iain Jenkins (UK)
 - Mary O’Grady (IE)
 - Gavin Hall (Chair of CMDv)
- EGGVP:
 - Katelijne Smets (Kela Pharma NV)
 - Elsa Vecino (EGGVP)
- IFAH-Europe
 - Rose-Marie Molina (Merial)
 - Maud Romero (Ceva)
 - Remon van Aubel (MSD)
 - Kevin Yount (Bayer)
- Secretariat
 - Jaume Colomer (IFAH-Europe)/Janos Kovacs (EMA)



Plans for the JTF

- Initial Meeting – face-to-face
 - Subsequent Meetings and JTF work - electronically
 - Additional face-to-face meetings as necessary
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- Consider proposed topics/issues
 - Work out possible solutions
 - Take possible solutions to respective groups for input
 - Work out final positions
 - Encourage implementation



Possible topics

- Simplified process for administrative changes (especially for changes impacting multiple products)
- Reduce requirements and avoiding additional administrative burden
- Explore possibility for single (umbrella) variation concept to combine several/many variations into one
 - Topics were based on the initial proposals presented by industry at the Variations Workshop
 - Chosen based on input from both sides
 - Combination: areas causing the most burden/areas with the least challenges to finding solutions



First JTF meeting

- 6 March 2015, 10:30 – 15:00 at EMA, London
- Main Agenda points:
 - Introduction of members – get to know each other
 - Discuss Objectives of JTF – How JTF will work and what are the general objectives
 - Discuss and brain-storm possible topics list
- Brief recap of Meeting



Conclusions/Questions

- Thanks to everyone who helped in the JTF formation
- Thanks to all the JTF participants
- Thanks for everyone's consideration and support for the output from the JTF
- We're on the right track!

Thank you for your attention!
Questions?

